18.0 TEST METHOD RELIABILITY (REPEATABILITY/ REPRODUCIBILITY)

Due to the lack of validation studies to evaluate FETAX reliability with water/soil/sediment samples, an assessment of test method reliability with environmental samples could not be conducted.

18.1 Summary of Historical Positive and Negative Control Data

No historical control data for FETAX studies conducted with water/soil/sediment samples were located.

18.2 Limitations of FETAX in Regard to Test Method Reliability

Limitations in regard to test method reliability for studies conducted with environmental samples could not be identified.

18.3 Data Interpretation Issues

One potential issue affecting data interpretation connected with water/soil/sediment samples is the lack of an exogenous MAS incorporated into the FETAX assay. This is relevant when results are being extrapolated to estimate effects on adult organisms of the same species. Other data interpretation issues include the appropriateness of data handling and processing, and the lack of reference data for comparison.

18.4 Section 18 Conclusions

To provide data for evaluation, a validation study designed to evaluate the ecotoxicological applicability of FETAX would be helpful. Such a study should include assessments by several laboratories, and should include the testing of both common samples and environmental samples collected independently. Data from at least one reference species should be collected, and the

study design should include sites with different gradients of developmental toxicity. Studies focusing on data interpretation issues could also be helpful in further optimizing the assay. Potential issues to address include the decision criteria used for ranking samples in regard to developmental hazard, and the appropriateness of sample handling and processing techniques.